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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,756	02/12/1999	LAURIE H GLIMCHER	HUI-021CN	9168

959 7590 04/24/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	16

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/248,756	Applicant(s) GLIMCHER ET AL.	
	Examiner Gerald Leffers	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of an amendment, mailed 10/29/01 and entered as Paper No. 15. In Paper No. 15 applicants amended claim 35 and cancelled nonelected claims (claims 50-55). Claims 35-49 are pending in the instant application. This action is FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 38 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 5,958,671. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reasons provided in Paper No. 12. **This rejection is maintained for reasons of record in Paper No. 12 and in the remailed action of Paper No. 13.**

Response to Arguments

Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive. The response indicates that a terminal disclosure over the '671 patent was submitted with the response of Paper No. 15. Unfortunately, this paper has not been received by the Office

and matched with the file. The instant rejection will be withdrawn upon receipt of the terminal disclaimer.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in Paper No. 12 and in the remailed action of Paper No. 13.**

Response to Arguments

Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive. The response essentially argues: 1) the specification (i.e. page 7, line 32 through page 8, line 22) describes the structural and functional characteristics of a number of maf proteins sufficient to describe the broadly claimed genus, 2) the prior art does not disclose the relationship between the maf family of proteins and modulation of the immune response, 3) the specification describes screening assays which can be used in the instant methods (e.g. one- and two-hybrid assays, 4) the prior art teaches conventional methods of determining the affect of a test compound on the immune system, and 5) the examiner should provide evidence or reasons

why persons of skill in the art would not recognize in applicants' disclosure a description of the invention as defined in the pending claims.

While the specification does provide some guidance with regard to maf proteins concerning their putative structural characteristics and activities, this description is not sufficient to describe the broadly claimed genus of any "maf family" protein. This description of maf proteins provided in the specification is particularly inadequate with regard to the critical element of applicants' claimed invention: maf family proteins that are involved in some manner with an immune response. As admitted in the specification and applicants' response, there are no other teachings in the prior art indicating the relationship between maf proteins and the immune response. While the specification does provide some guidance with regard to screening assays, and while the prior art does provide guidance in general with regard to assays for measuring the immune response, these teachings are not provided in the context of a specific maf protein and its role in the immune response. The crux of applicants' arguments appears to be that because c-Maf is involved in regulating IL-4 expression in Th2 cells, a structural/functional basis exists for extrapolating this involvement of a single maf protein in immune response to any other maf family protein. There is no basis provided in applicants' specification or the prior art to support this extrapolation. The teachings cited by applicant do nothing to provide one of skill in the art to envision which maf family proteins are involved in any part of the immune response, much less a specific function of the immune response.

With regard to the statement that the examiner should provide evidence or reasons why a person skilled in the art would not recognize in the instant disclosure a description of the invention as defined in the pending claims, the examiner has provided a rational explanation as

to why one of skill in the art would not be able to envision a representative number of embodiments of the claimed invention (i.e. a given maf protein other than c-Maf involved with a specific aspect of the immune response that can be assayed with a specific assay) sufficient to describe the broadly claimed genus.

Claims 35-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for embodiments wherein the immune response assayed is the effect of the test compound on expression of an interleukin-4 gene and wherein the maf family protein is c-Maf, does not reasonably provide enablement for practicing the claimed invention with any other immune response and with any other maf family proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. **This rejection is maintained for reasons of record in Paper No. 12 and in the remailed action of Paper No. 13.**

Response to Arguments

Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive. The response essentially argues:1) the specification does teach immune response assays encompassed by the pending claims, 2) the specification teaches recombinant expression vectors, reporter genes and cell types that can be used in the screening assays encompassed by the rejected claims, 3) the step of identifying a compound that modulates and immune response is routine in the art and would not require undue experimentation, 4) the examiner has imposed the requirement of working examples to enable the breadth of the pending claims, and 5) a considerable amount of experimentation is permitted.

The response incorrectly characterizes the rejection as being directed towards a single step in the claimed method. The point the examiner was making with regard to the final step in the claimed methods is that there is no teaching of determining the effect of a compound on an immune response in light of a specific teaching of a maf family protein involved with a specific aspect of the immune response other than for c-Maf. This is not a requirement for a reduction to practice for every embodiment of the claimed invention, as suggested in applicants' response. However, some sort of teaching indicating the relationship of a specific maf family protein other than c-Maf with a specific aspect of the immune response would provide some level of predictability of practicing the claimed method with an expectation of success. Such a teaching could be base upon a scientific rational without any necessity for reduction to practice, providing the scientific basis for the expectation of a specific effect for a given maf family protein is sound. In the absence of such a teaching, and applicants' specification was well as the prior art have not provided such a teaching, actual reduction to practice would be helpful in establishing some predictability in practicing the claimed methods.

With regard to the cited teachings from the specification, the teachings appear to be primarily directed towards detection of proteins that interact with c-Maf (e.g. two-hybrid assays) or towards reporter assays wherein the sequence that is bound by c-Maf in Th2 cells is operatively linked to a promoter. The crux of applicants' argument appears to be that because c-Maf has been shown to be involved in the regulation of IL-4 gene expression, one can necessarily extrapolate that other maf family proteins are involved in some aspect of the immune response. The narrow teachings of the specification with regard to assays, vectors, etc. do not support this extrapolation to any other maf family protein.

With regard to the assertions concerning routine experimentation and a great deal of routine experimentation being permitted, these assertions are accurate as far as they go but are not persuasive with regard to the instant invention. The prior art and instant specification do not provide a scientific rational or reduction to practice to extrapolate the observations made for c-Maf and its regulation of IL-4 gene expression to any other maf family protein and any specific immune response. This makes practicing the instant invention unpredictable. Given the fact that one of skill in the art would have to first establish what aspect of the immune response, if any, is affected by a given maf family protein, and given that there is no basis provided by the instant specification or prior art to envision ahead of time which maf family protein is going to have what effect on the immune response of an individual, it would require undue, unpredictable experimentation to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 37-39, 41-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite in that the metes and bounds of the phrase "a Maf family protein" are unclear. **This rejection is maintained for reasons of record in Paper No. 12 and in the remailed action of Paper No. 13.**

The specification has not defined "Maf family protein" in such a way as to allow one skilled in the art to distinguish between a member of the "Maf family" of bZIP transcription factors (e.g. c-Maf) and a member of the broader super family of bZIP transcription factors (e.g.

AP-1) that would not be a Maf protein (e.g. c-Jun). While some transcription factors have been identified in the art as being "Maf" proteins (e.g. MafB, MafK, Nr1, etc.), it is unclear from the specification how one skilled in the art would determine whether a newly discovered AP-1 is a Maf family protein or not. The distinguishing characteristics of a Maf protein have not been provided in the specification and it is unclear that there are art recognized standards for identifying a Maf protein distinct from any other bZIP family of transcription factors, known and unknown.

Response to Arguments

Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive. The response essentially argues: 1) the specification clearly defines maf family proteins, and 2) the specification provides an example of a representative member of the family (i.e. c-Maf).

The assertion that the specification at the cited pages (pages 7-8) clearly defines what constitutes a maf family protein is inaccurate. The cited pages merely indicate that a number of different proteins have been identified by various practitioners as maf proteins without providing any common structural or functional characteristics as to what would qualify, for example, a particular AP-1-type protein as a "maf family" bZIP protein. The implication that the disclosure of a single embodiment of a maf protein makes clear what constitutes a "maf family" protein is inaccurate. Again, there is no structural or functional aspect of c-Maf that is pointed to by the instant specification or prior art that is necessarily diagnostic of a "maf family" protein. The metes and bounds of the rejected claims thus remain unclear.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
April 22, 2002

DAVID GUZO
PRIMARY EXAMINER